Claims

1. Use of a nucleic acid construct comprising at least one hormone responsive element (HRE) and a transgene for preparing an agent for gene transfer.

2. The use of claim 1, wherein the at least one HRE is functionally linked to the transgene or not.

3. The use of claim 1 or 2, wherein the transgene is selected from the group consisting of genes encoding a blood clotting factor, hormone genes, hormone receptor genes, growth factors, enzyme genes, genes encoding cytokines or lymphokines, genes encoding inhibitor substances, genes encoding substances that function as drugs or vaccines, and antisense sequences.

4. The use of claim 3, wherein the transgene is a gene encoding a blood clotting factor and the agent is suitable for treating hemophilia.

5. The of claim 4, wherein the human blood clotting factor is selected from the group consisting of factor VIII, factor IX, and von Willebrand Factor (vWF).

6. The use of claims 1 to 5, wherein the nucleic acid construct comprises 1 to 20, preferably 3 to 10 HRE(s).

7. The use of claim 1 to 5, wherein the at least one HRE is a steroid responsive element, preferably a progesterone responsive element (PRE).

8. The use of claim 5, wherein the HRE is a PRE and the blood clotting factor is factor IX, preferably the factor IX has a nucleotide sequence of 689 to 2071 of SEQ ID NO: 1.

9. The use of claim 5, wherein the HRE is a PRE and the blood clotting factor is factor VIII.

10. The use of claim 7 to 9, wherein the PRE has the double stranded DNA sequence comprised of the DNA sequences of SEQ ID NOs: 3 and 4.

11. The use of claims 1 to 10, wherein the construct further comprises functional DNA sequences selected from the group consisting of promoter sequences, enhancer sequences, silencer sequences, origin of replication sequences, integrational sequences, marker genes and switch sequences.

12. The use of claim 11, wherein the construct further comprises a tissue-specific promoter, preferably an α-antitrypsin promoter.

13. The use according to any one of claims 1 to 12, wherein the agent further comprises a hormone-hormone receptor complex, preferably a steroid-steroid receptor complex.

14. The use of claim 13, wherein the molar ratio of HRE within the nucleic acid construct to hormone receptor is from 1:1 to 1:10, preferably 1:2 to 1:5, and/or the molar ratio of hormone to hormone receptor is at least 1000:1, preferably at least 10000:1.

15. The use of claim 13 or 14, wherein the receptor is a progesterone

receptor and the steroid is progesterone or a progesterone derivative.

16. The use of claim 15, wherein the progesterone is natural micronized progesterone solubilized in a liphophilic matrix system and/or the progesterone receptor is hPR-A, hPR-B or comprises the nucleotide sequence of 557 to 933 SEQ ID NO: 9.

17. A nucleic acid construct comprising at least one HRE and a transgene, wherein one of said at least one HREs is not functionally linked to the transgene.

18. The nucleic acid construct of claim 17, which is as defined in claims 3 to 12.

19. A vector comprising the nucleic acid construct of claim 17 or 18.

20. A transformed cell or transgenic organism comprising the nucleic acid construct as defined in claims 17 or 18 or the vector as defined in claim 19.

21. A composition of matter comprising a nucleic acid construct comprising at least one HRE and a transgene as defined in claim 17 or 18 and/or a vector as defined in claim 19, said at least one HRE being coupled to a hormone-hormone receptor complex.

22. The composition of matter of claim 21, wherein the hormone-hormone receptor complex is as defined in claims 13 to 16.

23. The composition of matter of claim 21, wherein the transgene is a gene encoding a blood clotting factor.

24. The composition of matter of claim 21 wherein the blood clotting factor is factor IX.

25. The composition of matter of claim 21 wherein the blood clotting factor is factor VIII.

26. A method for preparing the composition of matter as defined in claim 21, which method comprises admixing the nucleic acid construct with the hormone receptor and the hormone.

27. A pharmaceutical composition comprising the nucleic acid construct of claim 17 or 18, the vector of claim 19, and/or the composition of matter of claim 21 to 25.

28. The pharmaceutical composition of claim 27, which is suitable for gene transfer, preferably for treating hemophilia.

29. A method for gene transfer which comprises administering the agent as defined in claims 1 to 16, or the composition of matter as defined in claims 21 to 25 to an organism or to a cellular system.

30. A method for delivering into an organism or into a cellular system a nucleic acid encoding a transgene to be expressed in the cells of the organism or the cells of the cellular system, which method comprises administering an agent as defined in claims 1 to 16 or composition of matter as defined in claims 21 to 25 to the organism or to the cellular system so that the hormone in the composition interacts with the cell membrane and therewith enhances diffusion and transport of the

nucleic acid that is coupled to the hormone-hormone receptor complex across the membrane and into the cell.

31. The method of claim 30, wherein a nucleic acid encoding human factor VIII or factor IX is delivered into the cell.

32. A method of treating blood clotting disorders comprising administering a therapeutically effective amount of the composition of matter of claim 23 to an organism or to a cellular system.

33. A method of treating hemophilia B, comprising administering a therapeutically effective amount of the composition of matter of claim 24 to an organism or to a cellular system.

34. A method of treating hemophilia A, comprising administering a therapeutically effective amount of the composition of matter of claim 25 to an organism or to a cellular system.

35. Use of a steroid hormone for preparing an agent for gene transfer.

36. The use of claim 35, wherein the steroid hormone is a natural micronized steroid hormone, preferably natural micronized progesterone.

37. The use of claim 36, wherein the natural micronized steroid hormone is solubilized in a lipophilic matrix system.

38. A method for gene transfer which comprises administering a nucleic acid construct to an organism or to a cellular system, wherein

the nucleic acid construct contains a transgene and is encapsulated in a steroid hormone.